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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,692	04/17/2001	Motokazu Watanabe	43888-098	2364

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 03/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,692

Applicant(s)

WATANABE ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claim Rejections - 35 USC § 112

1. Claims 2, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 2, lines 2-3: "one kind of" should be -- an additional --

2. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the newly cited English language translation of Yoshioka et al. (JP 10-227755) in view of newly cited Lee et al. (WO 95/13535 A1).

Addressing Claim 1, Yoshioka et al. teach a glucose sensor (paragraph [0009] of the *Detailed explanation of the invention*) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (7) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1), formed in contact or in the vicinity of the electrode system (Figure 2).

Yoshioka et al. do not mention gluconic acid being present in the reaction layer in the absence of sample. It should be first noted that this limitation appears to be a negative desired result rather a structural limitation. So, this limitation does not appear to further limit the claim. Assuming the condition of gluconic acid being present in the reaction layer in the absence of

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sample to be a valid structural limitation, the claim is still obvious. Lee et al. teach a calibrant solution (not a "sample") for glucose sensors comprising glucose (the abstract and page 3, lines 14-19). It would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the calibrant solution of Lee et al. to the glucose sensor of Yoshioka et al. to calibrate the sensor *before measuring samples* because as taught by Lee et al. diabetics need an accurate reading of their glucose level (page 1, lines 19-25 and page 3, lines 20-26). When the glucose in the calibrant solution reacts with the glucose dehydrogenase in the reaction layer gluconic acid will also be present in the reaction layer since gluconic acid is a product of the activity of glucose dehydrogenase when it reacts with glucose (CAPLUS abstract of Howaldt et al. ("A continuous enzyme membrane reactor retaining the native nicotinamide cofactor 'NAD(H)'", Ann. N. Y. Acad. Sci. (1990), 589(Biochem. Eng. 6), 253-60) and Woodward et al. (US 5,942,424) Figure 1 and column 3, lines 19-24).

Addressing Claim 3, the preferred form of Lee et al.'s calibrant comprises calcium ions (page 10, line 20 – page 11, line 20).

Addressing Claims 5 and 10, Yoshioka et al. disclose suitable electron mediators in paragraph [0006].

Addressing Claim 8, since the preferred form of Lee et al.'s calibrant comprises calcium and sodium ions (page 10, line 20 – page 11, line 20), when gluconic acid results from the

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glucose dehydrogenase acting on glucose the gluconic acid will dissociate to form a calcium or sodium gluconate salt.

7. Claims 1, 4, 5, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the newly cited English language translation of Yoshioka et al. (JP 10-227755) in view of newly cited English language translation of Akio et al. (JP 09-262086).

Addressing Claim 1, Yoshioka et al. teach a glucose sensor (paragraph [0009] of the *Detailed explanation of the invention*) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (7) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1), formed in contact or in the vicinity of the electrode system (Figure 2).

Yoshioka et al. do not mention gluconic acid being present in the reaction layer in the absence of sample. It should be first noted that this limitation appears to be a negative desired result rather a structural limitation. So, this limitation does not appear to further limit the claim. Assuming the condition of gluconic acid being present in the reaction layer in the absence of sample to be valid structural limitation, the claim is still obvious.

Akio et al. teach adding gluconic acid to a reaction layer containing glucose dehydrogenase so as to enhance the stability of the reaction layer (the abstract; *Technical Problem*; and paragraphs [0014]-[0016] of *Means*).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to add gluconic acid to the reaction containing glucose dehydrogenase as taught by

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Akio et al. in the invention of Yoshioka et al. because as taught by Akio et al. the stability of an immobilized enzyme can be saved for a long period of time (*Effect of the Invention*), thereby preserving the ability of the sensor to make accurate measurements.

Addressing Claim 4, Akio et al. disclose using a sodium or potassium salt of gluconic acid in claim 4, for example.

Addressing Claims 5 and 11, Yoshioka et al. disclose suitable electron mediators in paragraph [0006].

Allowable Subject Matter

8. Claims 2, 6, and 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

- a) Claim 2: the combination of limitations requires that the reaction layer to contain an additional additive to gluconic acid selected from the Markush group of claim 2; and
- b) Claim 6 and 9 depend from allowable claim 2.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguera

Alex Noguera

March 17, 2003